

1 Ramon Rossi Lopez - rlopez@lopezmchugh.com
(California Bar Number 86361; admitted *pro hac vice*)
2 Lopez McHugh LLP
100 Bayview Circle, Suite 5600
3 Newport Beach, California 92660
949-812-5771

4 Mark S. O'Connor (011029) – mark.oconnor@gknet.com
5 Gallagher & Kennedy, P.A.
2575 East Camelback Road
6 Phoenix, Arizona 85016-9225
602-530-8000

7 *Co-Lead/Liaison Counsel for Plaintiffs*
8

9 UNITED STATES DISTRICT COURT

10 DISTRICT OF ARIZONA

11 In Re Bard IVC Filters Products
12 Liability Litigation

No. MD-15-02641-PHX-DGC

**PLAINTIFFS' RESPONSE IN
OPPOSITION TO DEFENDANTS'
MOTION TO AMEND AND CERTIFY
THE COURT'S NOVEMBER 22, 2017
ORDER FOR INTERLOCUTORY
APPEAL PURSUANT TO 28 U.S.C.
§1292(b)**

(Assigned to the Honorable David G.
Campbell)

13
14
15
16
17
18
19 Plaintiffs oppose Defendants' C.R. Bard, Inc.'s and Bard Peripheral Vascular, Inc.'s
20 (collectively "Bard's") Motion to Amend and Certify the Court's November 22, 2017
21 Order ("Motion"). In support of this Opposition, Plaintiffs submit the following
22 Memorandum of Points and Authorities.

23 **MEMORANDUM OF POINTS AND AUTHORITIES**

24 Bard's Motion to Amend and Certify the Court's November 22, 2017 Order
25 regarding preemption should be denied because Bard cannot meet all three certification
26 requirements under 28 U.S.C. §1292(b). Bard attempts to re-package its original
27 argument—for which it produced no supporting evidence—that this case was different
28 from any other cases involving 510(k)-cleared products for which preemption was denied,

1 that its products' histories were different than other 510(k) reviewed devices, that
 2 *Medtronic v. Lohr* is now superseded¹, and that its products had received FDA review
 3 equivalent to the PMA process such that preemption should be applied despite *Lohr*'s
 4 holding. For the reasons set forth below, Bard's Motion to Amend and Certify the Court's
 5 November 22, 2017 Order should be denied.

6 The Ninth Circuit has long held "[t]hat §1292(b) is to be applied sparingly and only
 7 in exceptional cases[.]" *United States v. Woodbury*, 263 F.2d 784, 788 (9th Cir. 1959); *see*
 8 *also Villarreal v. Caremark LLC*, 85 F. Supp. 3d 1063, 1067 (D. Ariz. 2015)(stating that
 9 Congress did not intend for the courts to abandon the final judgment doctrine and embrace
 10 the principle of piecemeal appeals). The party seeking interlocutory appeal bears the
 11 burden of demonstrating three criteria. *Couch v. Telescope, Inc.*, 611 F.3d 629, 633 (9th
 12 Cir. 2010); *Fukuda v. County of Los Angeles*, 630 F. Supp. 228, 229 (C.D.Cal.
 13 1986)(stating that the moving party has the burden of showing exceptional circumstances
 14 justifying departure from the basic policy of postponing appellate review until final
 15 judgment). The three criteria are: (1) that there is a controlling question of law, (2) that
 16 there are substantial grounds for difference of opinion, *and* (3) that an immediate appeal
 17 may materially advance the ultimate termination of the litigation. *In re Cement Antitrust*
 18 *Litig.*, 673 F.2d 1020, 1026 (9th Cir. 1982).

19
 20
 21 ¹ Bard argues that "*Lohr* only decided express preemption under the now-superseded 510(k)
 22 process in place in 1982." Def. Reply Papers (Doc. 7828), at 16. This argument has been
 23 made to other courts with the same result this Court reached. Specifically, where other IVC
 24 filter defendants claim *Lohr* is superseded — that the SMDA 1990 materially changed
 25 medical device regulation and specifically increased the robustness of the 510(k) process
 26 by incorporating a safety and effectiveness review of each medical device undergoing
 27 510(k) review — the courts have met the argument with rulings that include doubt that the
 28 Supreme Court has changed its clear position on 510(k) review based on the SMDA. "In
 fact, any changes imposed by the SMDA, which had already been in place for six years at
 the time of the *Lohr* decision, were available to the Court in interpreting Congress's intent
 for 510(k)." *Hovey v. Cook Inc.*, 97 F.Supp.3d 836, 845-846 (S.D. W.Va. 2015)(finding that
 these arguments "do not persuade me to abandon the Supreme Court's clear position on this
 matter."); *See also, In re: Cook Medical Inc., IVC Filters Marketing, Sales Practices and*
Product Liability Litigation MDL 2570, No. 1:14-ml-02570-RLY-TAB MDL No. 2570
 (S.D. Ind., Sep. 25, 2017); *Horrillo v. Cook, Inc.*, 2014 WL 8186704 (S.D. Fla, Jun. 6,
 2014).

1 These three requirements are jurisdictional. If the moving party cannot satisfy all
2 three, the Ninth Circuit must reject a §1292(b) appeal even if the district court has certified
3 it. *Couch*, 611 F.3d at 633. Even if the Court were to issue the requested certification, the
4 Ninth Circuit nevertheless “has discretion to reject the interlocutory appeal, and does so
5 quite frequently.” *James v. Price Stern Sloan, Inc.*, 283 F.3d 1064, 1068 n.6 (9th Cir. 2002).
6 In short, even if all three requirements are met, which clearly they are not, the Ninth Circuit
7 may still choose not to exercise jurisdiction. *Caterpillar Inc. v. Lewis*, 519 U.S. 61, 74, n.
8 10 (1996).

9 The decision to deny certification for interlocutory appeal is committed to the sound
10 discretion of the district court. *Villarreal*, 85 F. Supp. 3d at 1068. As such, even when a
11 party seeking certification satisfies all three statutory criteria, “district court judges have
12 ‘unfettered discretion’ to deny certification.” *Brizzee v. Fred Meyer Stores, Inc.*, 2008 WL
13 426510, at *3 (D. Or. Feb. 13, 2008)(quoting *Ryan, Beck & Co., LLC v. Fakih*, 275 F.
14 Supp. 2d 393, 396 (E.D.N.Y. 2003)). The sparing use of this exception and resulting
15 appeals are “hen’s-teeth rare.” *Hightower v. Schwarzenegger*, 2009 WL 3756342, at *2
16 (E.D. Cal. Nov. 6, 2009)(quoting *Camacho v. Puerto Rico Ports Authority*, 369 F.3d 570,
17 573 (1st Cir.2004). Moreover, a district court’s decision whether to certify its order under
18 28 U.S.C. § 1292(b) is unreviewable by the appellate court. *Executive Software N. Am.,*
19 *Inc. v. United States Dist. Ct. for the Cent. Dist. of Cal.*, 24 F3d 1545, 1550 (9th Cir. 1994).

20 On the rare occasion interlocutory appeals are heard and granted at the appellate
21 level, it is because there are unique circumstances including a split in authority amongst
22 the circuit courts and the district court’s challenged decision conflicts with the decisions of
23 several other courts, which is inapposite to the circumstances here. *In re Cintas Corp.*
24 *Overtime Pay Arbitration Litig.*, 2007 WL 1302496, at *2 (N.D. Cal. May 2, 2007). Bard
25 fails to show that the Court’s summary judgment Order regarding preemption created the
26 exceptional circumstance in which an immediate appeal is appropriate, nor can Bard’s
27 preemption argument satisfy the three criteria for certification for interlocutory appeal.
28

1 **A. Bard’s Alleged Controlling Question of Law Is One of Fact and Law, Not Pure Law**

2
3 Bard’s broad and sweeping contention that “federal preemption” is a question of
4 pure law represents a startling about-face from its original motion for summary judgment.
5 That motion framed preemption as a fact-dependent inquiry, purportedly necessitating two
6 declarations and a statement of facts running to more than 800 paragraphs. Bard further
7 insisted that the Court delve deeply into the regulatory history of Bard’s filters. Now, Bard
8 takes the direct opposite position and presents preemption as a generalized legal question;
9 one not of pure law.

10 A controlling question of law means “a ‘pure question of law,’ not a mixed question
11 of law and fact, or an application of law to a particular set of facts.” *Brizzee*, 2008 WL
12 426510, at *4 (D. Or. Feb. 13, 2008)(citing *Ahrenholz v. Bd. of Trs. of the Univ. of Illinois*,
13 219 F3d 674, 675–77 (7th Cir. 2000). The first criterion described as a controlling
14 “question of law” does not mean applying settled law to fact as Bard attempts to do here.
15 *Simmons v. Akanno*, 2011 WL 1566583, at *3 (E.D. Cal. Apr. 22, 2011) (citing *Ahrenholz*,
16 219 F.3d 674, 676). Nor does it mean a question that would require “rooting through the
17 record in search of the facts or of genuine issues of fact.” *Id.*, at *3.

18 Rather, what is contemplated under the §1292(b) exception is more of an abstract
19 legal issue that might arise, *i.e.*, a matter of pure law a court of appeals can resolve quickly
20 and easily without having to study the record. *See id.* Some examples of controlling
21 questions of pure law include fundamental issues like determining the proper parties,
22 proper jurisdiction, or when state or federal law should apply. *Woodbury*, 263 F.2d at 787;
23 *Villarreal*, 85 F. Supp. 3d at 1068; *see also Heaton v. Soc. Fin., Inc.*, 2016 WL 232433 at
24 *3 (N.D. Cal. Jan. 20, 2016).

25 Under no circumstances should an appellate court have to “delve beyond the surface
26 of the record” in order to examine facts. *Hightower v. Schwarzenegger*, 2009 WL 3756342,
27 at *2 (E.D. Cal. Nov. 6, 2009)(quoting *McFarlin v. Conseco Services, LLC*, 381 F.3d 1251,
28 1259 (11th Cir. 2004)). That is because the alleged controlling question must be a legal

1 question and one that “must be stated at a high enough level of abstraction to lift the
2 question out of the details of the evidence or facts.” *McFarlin*, 381 F.3d at 1259. The
3 “antithesis of a proper §1292(b) appeal is one that turns on whether there is a genuine issue
4 of material fact.” *Id.*

5 The Supreme Court recognizes that the §1292(b) exception was created as a “safety
6 valve for ‘serious legal questions taking the case out of the ordinary run.’” *Estate of*
7 *Kennedy v. Bell Helicopter Textron, Inc.*, 283 F.3d 1107, 1116 (9th Cir. 2002)(quoting
8 *Digital Equipment Corp. v. Desktop Direct, Inc.*, 511 U.S. 863, 883 (1994)). Bard cannot
9 meet this criterion because it based its motion for summary judgement on what it contended
10 was a uniquely detailed factual record of communications between itself and the FDA.

11 Bard’s mantra from the first moment in seeking preemption of all Plaintiffs claims
12 has been the uniqueness of the facts of the 510(k) review of its retrievable IVC filters, as
13 demonstrated by its 239 exhibits underlying 818 statements of fact it presented to the Court
14 in support of its Motion for Summary Judgment Regarding Preemption. It repeatedly
15 insisted that the Court conduct a necessarily factually specific “careful comparison” of the
16 regulatory history of Bard’s filters to decide Bard’s summary judgment motion. *See*, ECF.
17 No. 5396, at 13-14; ECF No. 7828 (Bard’s facts allege that this case involves an elevated
18 and exceptional level of FDA review imposing device-specific requirements.). In its
19 current papers Bard again reiterates that its alleged unique factual record is what
20 purportedly sets it apart from other preemption cases. Motion, at 4 (arguing that this case
21 uniquely involves a “developed factual record, special controls, device-specific Guidance,
22 history of down classification, and extensive regulatory review associated with Bard’s IVC
23 filters”). Yet factual issues are not subject to interlocutory appeal. *See e.g., Simmons*, 2011
24 WL 1566583, at *3 (stating “[t]he antithesis of a proper §1292(b) appeal is on that turns
25 on whether there is a genuine issue of fact, or whether the district court properly applied
26 settled law to the facts...”)(internal quotation and citation omitted); *Hightower*, 2009 WL
27 3756342, at *2; *Brizzee*, 2008 WL 426510, at *4.

1 Bard's alleged controlling question of law would require the Ninth Circuit to delve
 2 into the massive record of evidence this Court has already reviewed in reaching its sound
 3 decision. This is exactly the extensive factual review and re-screening of factual support
 4 that renders the §1292 exception inapplicable. *See Simmons*, 2011 WL 1566583, at *3;
 5 *Hightower*, 2009 WL 3756342, at *3. Moreover, Bard seeks to have well-settled U.S.
 6 Supreme Court preemption case law re-applied to its factual record essentially seeking a
 7 re-interpretation of controlling case law directly contrary to its position. *See, Simmons*,
 8 2011 WL 1566583, at *3. Accordingly, Bard fails to articulate a controlling issue of pure
 9 law and fails the first criterion.

10 **B. Bard Has Not Identified Substantial Grounds For Difference of Opinion**

11 In determining whether to certify a decision for appeal, the district judge is to
 12 analyze the strength of the arguments in opposition to the challenged ruling to decide
 13 "whether the issue for appeal is truly one on which there is a substantial ground for
 14 dispute." *Barrer v. Chase Bank, USA, N.A.*, 2011 WL 1979718, at *4–5 (D. Or. May 18,
 15 2011)(denying motion to certify)(quoting *In re Flor*, 79 F.3d 281, 284 (2d Cir.1996)). An
 16 indicator of whether there are substantial grounds for disagreement on a question of law is
 17 that other courts have, in fact, disagreed. *Couch*, 611 F.3d at 633. A substantial ground for
 18 dispute exists where the challenged decision conflicts with the decisions of several other
 19 courts or where there is no controlling precedent in the jurisdiction. *In re Cintas Corp.*
 20 *Overtime Pay Arbitration Litig.*, 2007 WL 1302496, at *2 (N.D. Cal. May 2, 2007)
 21 (granting certification, *inter alia*, because there was a clear split in the circuit courts). Bard
 22 must show a difference in legal opinion in order to show substantial grounds for a
 23 difference of opinion. *Semeneck v. Ahlin*, 2010 WL 2510996, at *3 (E.D. Cal. June 17,
 24 2010). Where the party seeking appeal cannot produce any law to the contrary, it cannot
 25 show substantial grounds for difference of opinion worthy of appeal. *White v. Nix*, 43 F.3d
 26 374, 378 (8th Cir. 1994).

1 Nothing in the Court's detailed and well-reasoned decision indicated any substantial
 2 grounds for dispute, or even that the decision presented a close call.² Bard seems to rely on
 3 the difference between its view and the Court's as a basis for what it believes are substantial
 4 grounds for dispute which do not satisfy the second criterion. *See Semeneck*, 2010 WL
 5 2510996 at *3 (articulating that the difference of view between the challenging party and
 6 the challenged opinion is not a basis for a difference of opinion to satisfy the second
 7 criterion of a §1292(b) challenge); *Hightower*, 2009 WL 3756342 at *4 (stating that a
 8 party's difference between his view and the court's ruling does not give rise to substantial
 9 grounds for dispute under a §1292(b) appeal); *Ass'n of Irrigated Residents v. Fred Schakel*
 10 *Dairy*, 634 F. Supp. 2d 1081, 1090-91 (E.D. Cal. 2008)(stating that disagreement with the
 11 Court's ruling does not create a substantial ground for difference).

12 Moreover, Bard fails to point to any split in the circuits or lack of precedent. Nor
 13 has Bard shown that the Court's ruling is inconsistent with any reported decisions. That is
 14 because it is not; the Court followed United States Supreme Court precedent in *Lohr*³ and
 15 *Riegel*.⁴ The only cases that are on point as to Bard's preemption argument—that the 510(k)
 16 review process has allegedly changed since *Lohr* and purportedly now incorporates safety
 17 and effectiveness determinations—are three district court cases *Horrillo*, *Hovey*, and *Cook*.
 18 These three cases unanimously found that *Lohr* is the precedent for these sorts of express
 19 preemption challenges and that no such change in 510(k) review process has taken place;
 20 it is still based on substantial equivalence and still focused on the status quo. Consequently,
 21 this is not a situation where courts facing this argument have produced disparate rulings.
 22 The Court in its Order essentially agreed with the holdings in these cases; *Lohr* is not out
 23 dated. *See*, ECF No. 8872.

24
 25
 26 ² *See Simmons v. Akanno*, 2011 WL 1566583, at *4 (E.D. Cal. Apr. 22, 2011)(considering
 27 a review of the challenged decision did not reveal substantial grounds for difference of
 28 opinion and neither did re-review); *Hightower v. Schwarzenegger*, 2009 WL 3756342, at
 *4 (E.D. Cal. Nov. 6, 2009)(same).

³ *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

⁴ *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

1 In what may be an attempt to point out some sort of split in the circuit courts, Bard
 2 repeatedly cites to dicta from a single circuit court opinion, *Caplinger v. Medtronic*, 784
 3 F.3d 1335 (10th Cir. 2015). But *Caplinger* does not support Bard's position. First,
 4 *Caplinger* is inapplicable; it dealt with a PMA-approved medical device, not the 510(k)
 5 process. Yet even if *Caplinger* were on point, "just because counsel contends that one
 6 precedent rather than another is controlling does not mean there is such a substantial
 7 difference of opinion as will support an interlocutory appeal." *Couch*, 611 F.3d at 633. A
 8 single, inapplicable case does not establish a split amongst the circuits, particularly where
 9 the Supreme Court has established the clear law be applied and other courts issuing
 10 opinions that are actually on point, including this Court, agree.

11 Thus, Bard cannot satisfy the second criterion either. Rather than identify substantial
 12 grounds for disagreement, it has simply stated its own disagreement with the Court's ruling
 13 and its assumption of what the Ninth Circuit wishes to hear. Neither is an acceptable basis
 14 to grant certification.

15 C. **Immediate Appeal Will Not Materially Advance the Ultimate**
 16 **Termination**

17 A party seeking interlocutory certification must show that an immediate appeal may
 18 "materially advance the ultimate termination of the litigation. *In re Cement Antitrust Litig.*,
 19 673 F.2d at 1026. When litigation will continue in substantially the same manner regardless
 20 of a decision, an appeal cannot be said to materially advance the ultimate termination of
 21 the litigation. *Hightower*, 2009 WL 3756342, at *4–5 (citing *White*, 43 F.3d at 378–379).
 22 There is no guarantee an interlocutory appeal will be accepted because Bard would still
 23 have the burden to persuade the Ninth Circuit that exceptional circumstances justify a
 24 departure from the practice of postponing appellate review until after the entry of final
 25 judgment. *Id.*

26 Under the second criterion, a district court judge must analyze the strength of the
 27 arguments in opposition to the challenged ruling. *Barrer*, 2011 WL 1979718, at *4–5. Part
 28 of the weakness in Bard's argument regardless of its alleged uniqueness with regard to

1 facts, special controls, regulatory history or anything else, is that under no previous
 2 circumstances has a design defect claim ever been preempted with regard to a 510(k)-
 3 cleared product. Even in the early “menstrual tampon cases”⁵ where failure to warn claims
 4 were preempted based on compliance with warning language promulgated by the FDA and
 5 found in a specific counterpart regulation, design defect claims were not preempted. Bard
 6 cites to no case law where a special control guidance document has ever preempted a failure
 7 to warn or design defect claim associated with a 510(k)-cleared medical device⁶. Even if
 8 *Degelmann*⁷ were still good law, there was no preemption with regard to product liability
 9 claims (as opposed to state consumer protection and false advertising claims), and it would
 10 provide no precedent to preempt the Plaintiffs failure to warn and design defect claims, as
 11 the Court recognized. *See* Order at 21.

12 Additionally, Bard would have the Ninth Circuit compare the guidance document
 13 applicable to all IVC filters to the guidance document at issue in the now vacated
 14 *Degelmann* matter, a comparison that would require a deep dive into the factual record.
 15 This is a far cry from examining a pure question of law. As such, the litigation would not
 16 be terminated and would in fact soldier forward as currently scheduled.

21 ⁵ This line of successful preemption challenges associated with 510(k) devices (menstrual
 22 tampons) with specific counterpart regulations promulgated by FDA (with verbatim,
 23 disease-specific warning language) only preempted failure to warn claims. Where the
 24 regulation was silent as to design or construction, design defect claims survived preemption
 challenges. *Papike v. Tambrands Inc.*, 107 F.3d 737, 740-41 (9th Cir. 1997; *see also*, *Moore*
v. Kimberly-Clarke, 867 F.2d 243, 246 (5th Cir. 1989).

25 ⁶ In its underlying motion Bard relied on *Tuttle v. CIBA Vision Corp.* 2007 WL 677134 (D.
 26 Utah 2007) in support of its argument that special control documents are federal
 27 requirements. Yet the *Tuttle* court provided no analysis of special controls. Instead it
 28 accepted the factual allegations that specificity of the guidance document and that the
 proposed warnings had been reviewed and accepted by the FDA as *undisputed*, and the
 design defect claims were not preempted but rather dismissed for lack of appropriate
 evidence. *Tuttle*, 2007 WL 677134 at *1-22 (emphasis added).

⁷ *Degelmann v. Advanced Med. Optics, Inc.*, 659 F.3d 835, 838–39 (9th Cir. 2011), *vacated*,
 699 F.3d 1103 (9th Cir. 2012).

1 RESPECTFULLY SUBMITTED this 12th day of December, 2017.

2 GALLAGHER & KENNEDY, P.A.

3 By: /s/ Mark S. O'Connor
4 Mark S. O'Connor
5 2575 East Camelback Road
6 Phoenix, Arizona 85016-9225

7 LOPEZ McHUGH LLP
8 Ramon Rossi Lopez (CA Bar No. 86361)
9 (admitted *pro hac vice*)
10 100 Bayview Circle, Suite 5600
11 Newport Beach, California 92660

12 *Co-Lead/Liaison Counsel for Plaintiffs*

13 **CERTIFICATE OF SERVICE**

14 I hereby certify that on this 12th day of December, 2017, I electronically
15 transmitted the attached document to the Clerk's Office using the CM/ECF System for
16 filing and transmittal of a Notice of Electronic Filing.

17 /s/ Gay Mennuti

18 6340602